

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study
<b>AUTHORS</b>	Pelzang, Rinchen; Hutchinson, Alison

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Peter Lachman ISQua, Ireland and UK
<b>REVIEW RETURNED</b>	27-Mar-2018

<b>GENERAL COMMENTS</b>	<p>The paper is well written and easy to follow. I think you have provided a template for others resource poor countries to follow as they contemplate the challenges to the development of a patient safety system.</p> <p>I think that you could consider adding the following to increase the generalisability of your findings beyond Bhutan</p> <ul style="list-style-type: none"><li>- a table of what a country needs to do to replicate the study elsewhere</li><li>- recommendations on how the local hospitals and centres could start measuring to validate the findings that you have uncovered. A lot of the findings are unsubstantiated and could easily be validated. For each of the identified safety areas you could recommend a solution</li></ul> <p>I think that if in each of the defined areas that were identified by the people you interviewed there was a measure that you recommend to take the outcomes to the next level would add value to your paper and strengthen your findings with practical interventions to follow.</p> <ul style="list-style-type: none"><li>- For example in a clinical area a rapid review of prescriptions over one week for prescribing errors could then give a measurement of prescribing errors over time etc.</li><li>- A safety cross could be used to identify the number of falls, infections, pressure ulcers. These interventions are resource light, do not need IT and are easily adaptable for resource poor settings.</li></ul>
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<b>REVIEWER</b>	Martie van Beuzekom Leiden University Medical Centre the Netherlands
<b>REVIEW RETURNED</b>	04-Apr-2018

<b>GENERAL COMMENTS</b>	<p>Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study</p> <p>The issue of the manuscript to present patient safety concerns in Bhutan's healthcare system is very important, but I have some questions/comments about the manuscript.</p>
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	<p>In common It would be interesting to read if whether there were differences between hospitals and disciplines about safety issues and concerns</p> <p>Study design Explain more what this means</p> <p>Settings and participants In which year the study took place? I table with the participants description makes it more readable</p> <p>Data collection procedure Advise to add the nominal group task statement form as attachment</p> <p>Results Medication error: most common, it is possible to indicate how often this was mentioned. The same for surgical errors: some instances. Diagnostic errors: were perceived as common, does this mean that every nurse and doctor and manger mentioned this item.</p> <p>Human (staff) and system factors: this topic is not discussed in the introduction, there for more explanation is needed</p> <p>Table 2 Discuss why the classification: knowledge etc. was chosen</p> <p>References Why is there no reference to your dissertation included: Patient safety issues and concerns in Bhutan’s healthcare system: A qualitative study</p>
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**VERSION 1 – AUTHOR RESPONSE**

Reviewer 1

I think that you could consider adding the following to increase generalisability of your findings beyond Bhutan:

A table of what a country needs to do to replicate the study elsewhere

We are not clear about this request from the reviewer. The methods for the study are described in detail within the methods section of the manuscript and we believe they are sufficient to enable others to replicate the study. We seek the editor’s guidance on whether/how we should respond to this recommendation.

Recommendations on how the local hospitals and centres could start measuring to validate the findings that you have uncovered. A lot of findings are unsubstantiated and could easily be validated. For each of the identified safety areas you could recommend a solution.

Recommendations for hospitals and centres to measure quality and safety have been added to pages 27 to 29.

I think that if in each of the defined areas that were identified by the people you interviewed there was a measure that you recommend to take the outcomes to the next level would add value to your paper and strengthen your findings with practical interventions to follow. – for example, in clinical area a rapid review of prescriptions over one week for prescribing errors could then give a measurement of

prescribing errors over time. – a safety cross could be used to identify the number of falls, infections, pressure ulcers. These interventions are resource light, do not need IT and are easily adaptable for resource poor settings.

Recommendations to this effect have been added to pages 27 to 29.

#### Reviewer 2

In common it would be interesting to read if whether there were differences between hospitals and disciplines about safety issues and concerns

The intent of this study was not to identify differences among hospitals and disciplines. Rather, our intent was to capture a 'slice from the life world' as it is experienced by the participants. While an understanding of the differences among hospitals and disciplines would be valuable, we believe it is a subject for future research in this field.

#### Study design

Explain more what this means

As suggested by the reviewer, this has been amended on page 7 under subheading 'study design' to include the following text: 'The QED research approach assists researchers to gain an understanding of the real world context as it is experienced by the participants – i.e., what is working and what is not working. The approach enables the researcher to obtain a detailed account of the problem of concern and capture meaningful characteristics related to real life events. Most importantly, QED research is appropriate in situations where the problem is not known or the problem is too complex to be captured by other methods (e.g., questionnaire survey). QED research is considered to be a highly pragmatic approach that enables the answering of concrete and practical 'what' kinds of question, such as those addressed in this study.'

#### Settings and participants

In which year the study took place?

Added '2013' in the text on page 7.

Table with the participants description makes it more readable

Added a table to pages 8.

#### Data collection procedure

Advise to add the nominal group task statement form as attachment

Nominal group task statement form attached as supplementary material/data

#### Results

Medication error: most common, is it possible to indicate how often this was mentioned

The same for surgical errors: some instances

Because this qualitative exploratory descriptive study was designed to capture a 'slice from the life world' as it is experienced by the participants we did not count the responses for how often

medication errors or surgical errors were mentioned. We did, however, identify which participants and participant groups referred to the safety concern.

Diagnostic errors: were perceived as common, does it mean that every nurse, doctor and manager mentioned this item?

Across the disparate participant groups', when we refer to safety issues as common we mean that most (not everyone) of the participants across each category (nurse, doctor, manager and health assistants) referred to the error as a common patient safety issue and concern.

Human (staff) factors and system factors: this topic is not discussed in the introduction, therefore more explanation is needed

Thank you for pointing this out. The human (staff) factors and system factors are, now, briefly discussed in the introduction (pages 5-6) as follows: 'Most adverse events have been found to be associated with human (staff) factors and system (organisational) factors. Human (staff) factors include slips, lapses, violations and mistakes made by healthcare professionals (such as nurse, physicians, surgeons, pharmacists, anaesthetists) due to aberrant mental processes such as inattention, forgetfulness, carelessness, negligence, recklessness, poor motivation and lack of competency (knowledge, skills and attitude) (Reason, 1990;1995; 2000; 2004; 2005; Cronenwett, Sherwood, Barnsteiner, et al., 2007). In medical and nursing literature, competency is classified according to knowledge, skills and attitudes (Cronenwett, Sherwood, Barnsteiner, et al., 2007; Cowan, Norman & Coopamah, 2005; Chuenjitwongsa, Oliver, Bullock, 2018; Garside & Nhemachena, 2013; Madigosky, Headrick, Nelson, et al., 2006; Schall, Stone, Currie, et al., 2008). Knowledge relates to healthcare professionals' ability to recognise and understand the potential patient safety features and/or strategies (i.e., correctly prescribing medication - right drug, for the right reasons). Skills relate to healthcare professionals' ability to perform clinical tasks correctly to reduce risk of harm to patients (i.e., the correct preparation and administration of injections, the prevention of cross infection, accurately checking vital signs, and taking a full patient history). Finally, attitudes relate to healthcare professionals' ability to value the patient safety prevention strategies and follow them (i.e., value own role in preventing errors by following standard protocols). System (organisational) factors relate to the conditions under which individuals work and can be used to build defences to avert errors or mitigate their effects (Reason, 200). System (organisational) factors include effective patient safety and clinical governance, financial resources, educational system and hospital design.'

Table 2 discuss why the classification: knowledge ect. was chosen?

The theme 'lack of competency' (in Table 2) has been classified into knowledge, skills and attitudes because patient safety competency encompasses these elements. A brief discussion of this classification has been added to pages 5-6 under subheading 'Introduction' to indicate/clarify why competency has been classified into 'knowledge, skills and attitude' as follows: In medical and nursing literature competency is classified into knowledge, skills and attitude (Reason, 1990;1995; 2000; 2004; 2005; Cronenwett, Sherwood, Barnsteiner, et al., 2007). Knowledge relates to healthcare professionals' ability to recognise and understand the potential patient safety features and/or strategies (i.e., correctly prescribing medication - right drug, for the right reasons), while skills relates to healthcare professionals' ability to perform clinical tasks correctly to reduce risk of harm to patients (i.e., the correct preparation and administration of injections, the prevention of cross infection, accurately checking vital signs, and taking a full patient history), and attitude relates to healthcare professionals' ability to value the patient safety prevention strategies and follow them (i.e., value own role in preventing errors by following standard protocols).' [see also the above response]

## References

Why is there no reference to your dissertation included: Patient safety issues and concerns in Bhutan's healthcare system: A qualitative study?

The reference to my dissertation was included under the subheading 'strength and limitations' as "[author blinded]". As per your comment, the reference to my dissertation has now been included.

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Martie van Beuzekom LUMC, The Netherlands
<b>REVIEW RETURNED</b>	29-May-2018

<b>GENERAL COMMENTS</b>	It is unfortunate that although it is a qualitative exploratory descriptive study, the number of medication errors and surgical errors can not be mentioned, because in my opinion it is also very interesting information for other countries, but if it is not done it can not be delivered. The other comments were processed by the authors in the script
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<b>REVIEWER</b>	Peter Lachman ISQua Ireland
<b>REVIEW RETURNED</b>	01-Jun-2018

<b>GENERAL COMMENTS</b>	The paper reads well. I think you can add value by considering the latest publications from WHO which will add to the guidance in your your recommendations National Quality and Policy Strategy <a href="https://www.google.com/search?client=safari&amp;rls=en&amp;q=who+nqps&amp;ie=UTF-8&amp;oe=UTF-8">https://www.google.com/search?client=safari&amp;rls=en&amp;q=who+nqps&amp;ie=UTF-8&amp;oe=UTF-8</a> and Delivering quality health services A global imperative for universal health coverage by OECD/World Bank/WHO report launched last week at the World Health Assembly
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### VERSION 2 – AUTHOR RESPONSE

Reviewer 2

It is unfortunate that although it is a qualitative exploratory descriptive study, the number of medication errors and surgical errors can not be mentioned, because in my opinion it is also very interesting information for other countries, but if it is not done it can not be delivered. The other comments were processed by the authors in the script

While an understanding of the differences among hospitals and disciplines would be valuable, we believe it is a subject for future research in this field.

Reviewer 1

Please leave your comments for the authors below

The paper reads well. I think you can add value by considering the latest publications from WHO which will add to the guidance in your your recommendations

National Quality and Policy Strategy oe=UTF-8

and

Delivering quality health services A global imperative for universal health coverage by OECD/World Bank/WHO report launched last week at the World Health Assembly

We have added a sentence on page 27 and 29 and included the references, as suggested - see below:

" As recommended by the World Health Organisation,76 patient safety policy and strategy should be aligned with existing national priorities." (on page 27, last paragraph - last sentence)

" The mechanisms to assure, monitor and continually improve patient safety and quality of care must be built into the foundations of the health system (WHO, 2018)." (on page 29, first paragraph, 2nd sentence)